DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 18, 2014

Bioinflnity (M) Sdn, Bhd., LLC.
% Carrie Hetrick
Senior Consultant, RA
Emergo Group
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K141893
Trade/Device Name: Vibrance Kegel Device (VKD)
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: November 16, 2014
Received: November 21, 2014

Dear Carrie Hetrick,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K141893

Device Name
Vibrance Kegel Device (VKD)

Indications for Use *(Describe)*
The Vibrance Kegel Device (VKD) is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) Summary

for

Vibrance Kegel Device (VKD)

1. Submission Submitter

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3. Date Prepared

December 18, 2014

4. Device Identification

Trade/Proprietary Name:	Vibrance Kegel Device (VKD)
Common/Usual Name:	Perineometer
Classification Name:	Perineometer
Classification Regulation:	21 CFR § 884.1425
Product Code:	HIR
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device

Colonial Medical Supply Pelvic Muscle Therapy 510(k) Number K002830

6. Device Description

The Vibrance Kegel Device (VKD700) is an intra-vaginal exercise device intended to strengthen the pelvic floor musculature by offering resistance to an individual's voluntary contractions of these muscles. The Vibrance Kegel Device incorporates an active vibration

biofeedback mechanism for the identification of the pelvic floor muscles, and the sheaths provide graduated resistance levels for the progressive strengthening of the pelvic floor muscle.

The therapeutic effect is from the user using the device to exercise the pelvic floor muscles in accordance with the exercise program included in the instructions. The device provides biofeedback information that allows the user to verify the use of the correct muscles in the exercise routine and thus the effectiveness of the exercises undertaken. The device also includes a resistive component to the training program to strengthen the pelvic floor muscle via physiologic principles. The biofeedback mechanism works by directly sensing the force applied by the pelvic floor muscle.

The device consists of a Main Body and three Resistance Sheaths with varying degrees of stiffness. It has a PCB assembly, and is battery powered by two independent 3V CR 1220 Lithium Batteries operating on two independent, enclosed electronic circuits for the vibration biofeedback loop and the other for audio guided training. The maximum diameter of the Vibrance Kegel Device shaft is 2.4 cm. The maximum inserted length of the shaft is 6 cm.

Main Body
The chassis of the device consists of an Acrylonitrile Butadiene Styrene (ABS) plastic frame with the biofeedback mechanism. It is incorporated within a tubular sheath made of medical grade silicone rubber which encloses the whole chassis. This main body and resistance sheath are the parts of the device that directly contact the user's intra-vaginal cavity. The base of the tubular sheath and chassis are winged to prevent total ingestion of the device into the vaginal canal.

Resistance Sheath
Three Resistance Sheaths, each with varying levels of stiffness are included with the Vibrance Kegel Device. When a Resistance Sheath is placed over the Main Body, the challenge of the exercise is increased.

7. Indication for Use Statement

The Vibrance Kegel Device (VKD) is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence.

8. Substantial Equivalence Discussion

The following table compares the Vibrance Kegel Device to the predicate device with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – Comparison of Characteristics

Manufacturer	**Bioinfinity (M) Sdn. Bhd.**	**Colonial Medical Supply**
Trade Name	Vibrance Kegel Device	Pelvic Muscle Therapy (PMTx)
		
510(k) Number	K141893	K002830
Product Code	HIR	HIR
Regulation Number	21 CFR § 884.1425	21 CFR § 884.1425
Regulation Name	Perineometer	Perineometer
Indications for Use	The Vibrance Kegel Device (VKR) is intended for the strengthening of the pelvic floor muscles, which has been found to help women with urinary incontinence.	Pelvic muscle trainer assists the user to perform Kegel exercises, by offering resistance, which may help in the treatment of urinary incontinence.
Over the Counter (OTC)	Yes	Yes
Anatomical Sites	Vagina	Vagina
Feature	Resistive vaginal exerciser	Resistive vaginal exerciser
Target Population	Women with mild incontinence	Women with mild incontinence
Anatomical Site	Vagina	Vagina
Single Patient Device	Yes	Yes
Single Use or Reusable	Reusable	Reusable
Provided Sterile	Clean, but not sterile	Clean, but not sterile
Biofeedback display information	No	Numerical response to muscle contraction strength
Device Design	Handheld device consisting of a Main Body and three gradual Resistance Sheaths	Handheld pneumatically based device with vaginal silicone sensor
Material	Main Body: ABS Plastic, PCB Assembly, two low electrical energy coin cell batteries (CR1220) Sheaths: Medical grade silicone (polydimethysiloxane)	Vaginal Probe: Medical grade silicone (polydimethysiloxane) Tubing: Medical grade silicone (polydimethysiloxane) Monitor: Not known
RoHs Compliant	Yes	Not applicable
Operating Principle	Resistive pelvic floor strengthener	Resistive pelvic floor strengthener
Resistance Component	The Vibrance Kegel Device Electromechanical spring contact offers 3 levels of resistance sheaths with increasing stiffness	Balloon silicone sensor
Biocompatibility	Guidelines set forth in ISO 10993 testing results indicate the material is biocompatible, nontoxic, and well tolerated by mucosal membranes.	Guidelines set forth in ISO 10993 testing results indicate the material is biocompatible, nontoxic, and well tolerated by mucosal membranes.
Chemical Safety	Addressed by biocompatibility testing per ISO 10993	Addressed by biocompatibility testing per ISO 10993
Instructions for Use	Manual	Manual
Energy Use and/or	Energy is supplied by two independent	None – pneumatic device provides an

Manufacturer	Bioinfinity (M) Sdn. Bhd.	Colonial Medical Supply
Trade Name	Vibrance Kegel Device	Pelvic Muscle Therapy (PMTx)
Delivered	replaceable 3.0 Volt CR-1220 lithium /manganese dioxide (Li/MnO_2) Button Cell batteries	air pressure reading that measures the strength of the pelvic floor muscle contractions
Packaging	Device in sealed plastic bag and manual in cardboard box	Device in sealed plastic bag and manual in cardboard box
Dimensions	6 cm x 2 cm	7.5 cm x 3 cm

9. Non-Clinical Performance Data

The following testing has been performed to support substantial equivalence:

Mechanical Testing – Compression testing was conducted on the Vibrance Kegel Device to measure the forces required to vibrate the sensor for each of the three levels of resistance sheath. A pull off test was also conducted to evaluate how much force is needed for the sheath to be removed from the main body when the device is in use, but is adequate for removal of a sheath after use. A correlation measurement test was then conducted to evaluate the test results of the compression test. The mechanical testing concluded that the different components of the device would function properly and safely when exposed to loads and configurations representative of normal use.

Biocompatibility - The biological safety of the Vibrance Kegel Device was evaluated in accordance with ISO 10993-1:2009 and guidance document entitled *Blue Book Memo, G95-1, Use of International Standard ISO-10993, and Biological Evaluation of Medical Devices: Part 1: Evaluation and Testing*. Under these, for the stated indications for use, each component of the device's biological safety was evaluated for in vitro cytotoxicity, skin sensitization, and vaginal irritation.

- In Vitro Cytotoxicity test was performed according to ISO 10993-12 and ISO 10993-5, with the results suggesting that the test articles did not induce a cytotoxic effect.
- Skin Sensitization (Maximization Test) was performed according to ISO 10993-10, with the results suggesting that the device extracts did not produce skin sensitization in guinea pigs.
- Irritation (Vaginal Irritation Study) was performed on New Zealand White Rabbits according to ISO 10993-10, with the results showing that there were no significant clinical signs and gross findings in either the control or test group, and there were no mortalities.

Electromagnetic Compatibility - The Vibrance Kegel Device complies with the applicable voluntary standards which include IEC 60601-1 and IEC 60601-1-11. The Vibrance Kegel Device complies with these voluntary standards including IEC 60601-1 and IEC 60601-1-11 for Electrical Safety and for systems used in the home healthcare environment.

Risk Analysis - Formal Risk Assessment of the Vibrance Kegel Device was performed in accordance with ISO 14971. With respect to perceivable conditions in which the device would be subjected to a worst-case environmental or human error scenario, Bioinfinity believes the outcomes of these risks are considered acceptable within the context of ISO 14971, and that all potential risks have been mitigated to the lowest form.

Performance Testing Summary

As part of demonstrating safety and effectiveness of Vibrance Kegel Device and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Bioinfinity (M) Sdn. Bhd. completed a number of tests. The Vibrance Kegel Device meets all the requirements for overall design, biocompatibility, and electrical safety testing performance confirms that the output meets the design inputs and specifications. The Vibrance Kegel Device passed all testing stated above as shown by the acceptable results obtained.

The Vibrance Kegel Device complies with the applicable voluntary standards for biocompatibility. The device passed all the testing in accordance with national and international standards.

10. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device; or the device has the same intended use and different technological characteristics that can be demonstrated as substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the differences between the Vibrance Kegel Device and the predicate device do not raise any questions regarding its safety and effectiveness. The Bioinfinity (M) Sdn. Bhd. Vibrance Kegel Device, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.